

REMARKS/ARGUMENTS

As amended, Claims 1-7, 9-16 and 18-22 are pending in the present application. Claims 1 and 10 are currently amended, and Claim 8 is canceled in this amendment. Applicants respectfully request the Examiner to consider the following remarks.

Support for the amendments

Support for the amendment to claim 1 to incorporate the specific cryogenic liquid is found in Claim 8 as originally filed. Support for the amendment to Claim 10 to point out that the droplets are rapidly frozen using the claimed method is found on page 4, lines 28-29.

The 103 Rejections

The Examiner rejected Claims 1-16 and 18-22 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,470,202 (the "Buxton" reference). Applicants have amended the claims and respond as follows.

The present invention involves a system and a method for preparing drug particles. In the method of the present invention, a solution containing an effective ingredient is sprayed at or below the level of a cryogenic liquid so as to result in rapid freezing of the solution. Rapid freezing is an important feature of the present invention, because rapid freezing results in smaller particles and generally more stable particles than would be produced using gradual freezing.

Buxton teaches a process for freezing a liquid medium to produce spherical frozen particles, comprising introducing the liquid medium in the form of droplets beneath the surface of a cooling liquid which is maintained at a temperature lower than the freezing point of the liquid medium, and moving the cooling liquid in a direction opposite to that of the ascent of the droplets. It is important to point out that Buxton teaches only certain cooling liquids: trichloroethane, trichloroethylene, dichloromethane, diethyl ether or fluorotrichloromethane.


It is also important to point out that the Buxton reference teaches freezing the droplets gradually. For example, column 3, lines 15-17 of Buxton states, "as it rises the composition is gradually frozen so that the frozen spherical particles may be collected at or near the top of the column."

As amended, Claim 1 teaches the use of specific cryogenic liquids selected from the group consisting of carbon dioxide, nitrogen, ethane, propane, helium, argon, or isopentane. The Buxton reference does not teach or suggest the use of these specific liquids as the cooling liquid. Therefore, Claim 1 is not anticipated or obvious in view of Buxton. Since Claims 2-7 and 9 are dependent from Claim 1, those claims are not anticipated or obvious in view of Buxton either.

Applicants have also amended Claim 10 to recite that the spraying step of the claimed method rapidly generates frozen particles. As described above, Buxton does not teach or suggest rapid freezing, and in fact teaches that the particles are gradually frozen. Therefore, amended Claim 10 is not obvious in view of Buxton. Since Claims 11-16 and 18-22 depend either directly or indirectly from Claim 10, such claims are not obvious in view of Buxton either.

For these reasons, Applicants believe the present application now stands in condition for allowance. Early notification thereof is respectfully requested.

Respectfully submitted,


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